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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/550,173	04/14/00	OOE	N 2185-0424-SP

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EXAMINER	
DAVIS,K	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 09/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/550,173	Applicant(s) OOE ET AL.	
	Examiner Katharine F. Davis	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 July 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 11-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *9* is/are allowed.

6)☒ Claim(s) *1-3, 5-8 and 11-16* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This Office Action is in response to the Reply filed July 3, 2001. Claim 10 has been canceled. Claims 1-9 and 11-16 are pending in the instant application.

The objections to the specification are withdrawn in view of the substitute specification and Sequence Listing filed on July 3, 2001. The objection to claim 14, the rejection of claims 1-9 and 11-16 under 35 U.S.C. § 112, second paragraph and the rejection of claims 1-5, 9 and 11-15 under 35 U.S.C. § 102(b) (Bradfield *et al.*) are all withdrawn in view of the amendments to the claims and the remarks presented by Applicants in the Reply filed July 3, 2001. All rejections of claim 10 are withdrawn in view of the cancellation of the claim.

Drawings

The drawings filed on April 14, 2000 have been approved by the draftsperson.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-8 and 11-15 remain rejected under 35 U.S.C. 102(b) as being anticipated by Evans *et al.* (US Patent 5,298,429: IDS reference).This rejection is maintained for reasons of record in the previous Office Action mailed on January 3, 2001. Evans *et al.* teaches a mammalian cell containing non-endogenous DNA which expresses a hormone receptor (said receptor can be an intranuclear hormone receptor, estrogen receptor, androgen receptor and/or a thyroid hormone receptor) and a DNA sequence which expresses a hormone response element operatively linked to a reporter gene sequence. The test cell of Evans *et al.* is made by introducing into said cell plasmids which contain the non-endogenous DNA sequences and selection marker gene sequences for propagation of the plasmids in the test cells. The non-endogenous DNA sequences are eukaryotic sequences which are known in the art to have TATA box promoter sequences. The test cells are employed in a method for determining whether a substance is a hormone receptor agonist or a hormone receptor antagonist. The test cells are cultured in the presence of the substance and the expression of the reporter gene is monitored to assess transcription activity. The test cells with reagents for making and using the test cells can be contained in a kit. The elements in claims 1, 2, 5-8 and 10-15 read on the test cells and bioassay of Evans *et al.* (see entire document).

Applicants' arguments presented on pages 9-15 of the Reply have been carefully considered but have not been found to be persuasive. Applicants assert that the operative hormone responsive promoter/enhancer element described by Evans *et al.* is very different from the transcription control region of the instant invention because the element of Evans *et al.* includes additional sequences other than a ligand-responsive transcription control recognition sequence and a minimum promoter. The definition of the transcription control region provided by the instant specification (page 18 of substitute specification) indicates that the control region can contain other functional elements (sequences) related to transcription control. This definition does not require that the transcription control region of the instant invention be exclusive of all other transcriptional functional elements (sequences). Therefore the hormone responsive promoter/enhancer element(s) (full length MTV LTR and fragments of the rat GH gene fused to a tk promoter) described by Evans *et al.* still anticipate the transcription control region of the instant invention.

Applicants additionally assert that Evans *et al.* fails to provide a cell securely maintaining introduced DNA. Evans *et al.* teach that the cells can be produced by co-introducing the reporter plasmid and expression plasmid with either the calcium phosphate coprecipitation described by Wigler *et al.* (Cell 16:777-785 1979) or with the DEAE-dextran method described by Deans *et al.* (Proceedings of the National Academy of Science USA 81:1292-1296 1984). The DEAE-dextran method described by Deans *et al.* provides transient expression, however Wigler *et al.* teach a co-transformation system providing stable integration of any defined gene into cultured cells (see abstract of Wigler *et al.* and page 1296 of Deans *et al.*) No where in the article does Wigler *et al.* teach that selectable markers other than tk can not be used nor does Wigler *et al.*

acquiesce that the described method may fail to provide a cell having the introduced DNA securely maintained. Wigler *et al.* state that aprt was used as a selectable marker in unpublished experiments. In fact, Wigler *et al.* goes so far as to suggest the use of dominant acting mutant genes which confer drug resistance may extend the host range for co-transformation to any cultured cell (see page 784). Applicants argue further that Wigler *et al.* fails to describe whether genes introduced with the tk gene have the transcription control region of the instant invention. Wigler *et al.* evidences a method used by Evans *et al.* but the Wigler article itself is not the basis for rejection. Claims 1-3, 5-8 and 11-15 are anticipated by Evans *et al.* which does teach the transcription control region of the instant invention.

For both the reasons above and the reasons made of record in the previous Office Action mailed on January 3, 2001, the rejection of claims 1-3, 5-8 and 11-15 under 35 U.S.C. § 102(b) is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in 'section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 16 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Evans *et al.* (US Patent 5,298,429: IDS reference). This rejection is maintained for reasons of record in the previous Office Action mailed on January 3, 2001. Claim 16 requires that the plasmid encoding the receptor gene have a different selectable marker from the plasmid encoding the reporter gene. Evans *et al.* teaches cotransfection of both plasmids into the test cells however does not specifically teach that the cotransfected plasmids have different selection markers. It is well known in the art that when carrying out a cotransfection protocol it is advantageous to use different selection markers for each plasmid in order to be sure that each plasmid was successfully taken up by the cell. One of skill in the art would be motivated to use different selection markers as a control method in cotransfection protocols. Therefore it would have been obvious to a person of ordinary skill in the art at the time that the instant invention was made to use different selection marker genes for each plasmid when carrying out cotransfection protocols.

Applicants' arguments presented on pages 17 & 18 of the Reply have been carefully considered but have not been found to be persuasive. Applicants assert that one of ordinary skill in the art would not be motivated to recover a cell having securely maintained introduced DNA and argue that Evans *et al.* teaches systems for transient gene expression. However, the rejection is directed to the obviousness of using different selection marker genes for each plasmid when

carrying out cotransfection protocols. Therefore, it is considered that Applicants did not address the 103 rejection in the Reply. Furthermore, Applicants' arguments are the same as those used for the 102 argument and which were not found to be persuasive for the reasons set forth above.

Accordingly, for both the reasons above and the reasons made of record in the previous Office Action mailed on January 3, 2001, the rejection of claim 16 under 35 U.S.C. § 103(a) is maintained.

Conclusion

Claims 1-3, 5-8 and 11-16 are rejected. Claim 9 is allowed. Claim 4 is objected to as being dependent upon a rejected base claim but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katharine F. Davis whose telephone number is (703) 605-1195 with direct desktop RightFax (703) 746-5199. The examiner can normally be reached on Monday-Friday (8:30am-5:00pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Schwartzman can be reached on (703) 308-7307. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications. Any inquiry concerning the formalities of this application should be directed to Patent Analyst Dianiece Jacobs whose telephone number is (703) 305-3388. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Katharine F. Davis
September 23, 2001

ROBERT A. SCHWARTZMAN
PRIMARY EXAMINER

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